OCT 12 2007

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 9807.92.

The Assigned 510(k) Number is: K071561

1. Applicant Device Information:

Device Trade/Proprietary Name: Multiple Brand Names
Device Common Name: Handpiece, Air Powered, Dental
Device Classification Name: Handpiece, Air Powered, Dental
Review Panel: Dental
Product Code: EFB
Regulation Number: 872.4200
Device Class: I
Intended Use:
This device is an air-powered hand-held device, intended to prepare dental cavities for restorations, such as tooth body treatment, tooth drilling and tooth grinding of stomatology.

2. Submitter Information:

Establishment Registration Name and Address:
Beijin North Pole Dental Handpiece Co., Ltd
Standard Workshop, Area A
Beijing Airport Industrial Zone
Shunyi, Beijing, P.R.China

Contact Person of the Submission:
Diana Hong
Shanghai Mid-link Consulting Co., Ltd.
1441, 6th Avenue
San Francisco, California
94122
U.S.A
Email: Diana.hong@mid-link.net
Fax: 760 466 5084

3. Predict Device

PENG LIM High Speed Air Turbine Handpiece

K Number: K062947

Product Code: EFB

Intended Use:

The PENG LIM High Speed Air Turbine Handpieces are intended for removing carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations and restorations and polishing teeth.

Manufactured by

PENG LIM ENTERPRISE CO., LTD.
67 Hwa Rong Rd., 2nd Fl.,
Ku Shan Dist.
Kaohsiung, CHINA (TAIWAN)
Tel: 07-552-2995

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 12 2007

Beijing North Pole Dental Handpiece Company, Limited
C/O Ms. Diana Hong
General Manger
Shanghai Mid-Link Business Consulting Company, Limited
Suite 8D, No. 19 Lane 999,
Zhongshan No. 2 Road (s)
Shanghai 200030
CHINA

Re: K071561
Trade/Device Name: Hi-Speed Turbine Handipieces
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: September 17, 2007
Received: September 24, 2007

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

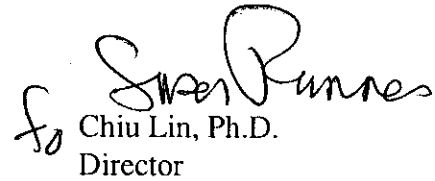
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K071561 ~~Pending~~

Device Name: Hi-Speed Turbine Handpieces

Indications for Use:
This device is an air-powered hand-held device, intended to prepare dental cavities for restorations, such as tooth body treatment, tooth drilling and tooth grinding of stomatology.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K071561